COMBINED TRANSMITTAL OF APPEAL BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES & PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. 1.136(a) (Large Entity)	Docket No. 112701-200

In Re Application Of: **Fuchs et al.**

Serial No.	Filing Date	Examiner	Group Art Unit
09/821,498	March 29, 2001	H. Prat	1761

Invention: **NUTRITIONAL COMPOUNDS AND METHODS OF IMPROVING PROTEIN DEPOSITION**

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TO THE COMMISSIONER FOR PATENTS:

This combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition for extension of time under 37 CFR 1.136(a) is respectfully submitted by the undersigned:

Signature Dated: **June 24, 2003**

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09/821,498	March 29, 2001	H. Prat	1761

Invention: **NUTRITIONAL COMPOUNDS AND METHODS OF IMPROVING PROTEIN DEPOSITION**

TO THE COMMISSIONER FOR PATENTS:

This is a combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition under the provisions of 37 CFR 1.136(a) to extend the period for filing an Appeal Brief.

Applicant(s) hereby request(s) an extension of time of (check desired time period):

☒ One month ☐ Two months ☐ Three months ☐ Four months ☐ Five months

from: **May 24, 2003** (*Date*) until: **June 24, 2003** (*Date*)

The fee for the Appeal Brief and Extension of Time has been calculated as shown below:

Fee for Appeal Brief:	$320.00
Fee for Extension of Time:	$110.00
TOTAL FEE FOR APPEAL BRIEF AND EXTENSION OF TIME:	**$430.00**

The fee for the Appeal Brief and extension of time is to be paid as follows:

☒ A check in the amount of **$430.00** for the Appeal Brief and extension of time is enclosed.

☐ Please charge Deposit Account No. in the amount of

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- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
- ☒ Any patent application processing fees under 37 CFR 1.17.

☒ If an additional extension of time is required, please consider this a petition therefor and charge any additional fees which may be required to Deposit Account No. **02-1818** .

#11

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Fuchs et al.
Appl. No.:	09/821,498
Filed:	March 29, 2001
Title:	NUTRITIONAL COMPOUNDS AND METHODS OF IMPROVING PROTEIN DEPOSITION
Art Unit:	1761
Examiner:	H. Prat
Docket No.:	112701-200

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted in support of the Notice of Appeal submitted by Appellants on March 24, 2003, in the above-identified patent application.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec S.A., by virtue of an Assignment recorded at the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants do not believe there are any known appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF THE CLAIMS

Claims 1-36 are pending in the patent application. A copy of the claims involved in this appeal is attached hereto as the Appendix. All of the claims were rejected in a Final Office Action dated February 12, 2003 (a copy of which is submitted herewith as Exhibit A).

IV. STATUS OF THE AMENDMENTS

All Amendments have been entered. There were no amendments filed subsequent to the Final Office Action.

V. SUMMARY OF THE INVENTION

The present invention relates to a composition for a nutritional supplement and methods for improving muscle protein synthesis, preventing muscle loss, and accelerating muscle mass recovery. The methods are especially beneficial for use with patients recovering from illness or surgery, those with limited appetite such as the elderly, anorexic patients, or those who have impaired ability to digest other sources of protein. The method includes the step of administering an effective amount of the composition. (Specification, page 1, lines 10-16.)

Various nutritional supplements are presently available. One family of supplements commonly found in North America is sold under the name ENSURE by Ross Laboratories. The protein source used in that product is predominantly caseinates and soy protein isolates. Another family which is commercially available is sold under the name RESOURCE by Novartis Nutrition Ltd. Once again, the protein source is based on caseinates. Still yet another family which is commercially available is sold under the name NUBASICS by Nestlé Clinical Nutrition. (Specification, page 2, lines 1-7.)

In general, the protein source used in products of this family is caseinate. However, it is found that these products suffer from the problem that they do not necessarily result in a consumer receiving sufficient nutrients; either because an insufficient amount of the product is consumed or insufficient other foods are consumed. This is especially the case with convalescing patients, the elderly and other anorexic patients where loss of appetite leads to insufficient nutrients being consumed. (Specification, page 2, lines 7-13.)

Nutritional supplements which are based on other protein sources, such as whey protein, are also available or have been described in the literature. In general, the nutritional supplements based upon whey protein are provided in the form of fruit juices; for example as described in European patent application 0486425 and US patent 5,641,531. However, these products suffer from the problem that they generally do not provide a lipid source despite the fact that lipids are essential for adequate nutrition. (Specification, page 2, lines 14-20.)

Accordingly, in a first aspect the invention provides a method for improving muscle synthesis comprising administering to an individual a therapeutically effective amount of a composition which comprises: (i) a protein source which provides at least about 8% and preferably at least about 10% total calories of the composition and which includes at least about 50% by weight of whey protein; (ii) a lipid source having an omega 3:6 fatty acid ratio of about 5:1 to about 10:1 and which provides at least about 18% of the total calories of the composition; (iii) a carbohydrate source which provides the remaining calories of the composition; and (iv) a balanced micronutrient profile comprising at least vitamin E and vitamin C. (Specification, page 2, line 27 - page 3, line 4.)

In a second aspect of the invention, a method of preventing muscle loss in an individual at risk of same is provided. The method includes administering a therapeutically effective amount of the above composition to the individual. In a third aspect of the invention, a method for accelerating muscle mass recovery in an individual is provided. The method includes administering a therapeutically effective amount of the above composition to the individual. (Specification, page 3, lines 8-13.)

In a fourth aspect, the invention provides a method of production of the composition which comprises blending the components in the required amounts. Surprisingly it has now been found that a composition for a nutritional supplement in accordance with the invention, because it contains whey protein, can produce at least a 2-fold increase in whole body protein deposition in elderly people as compared to casein as the protein source. Therefore it may help such patients conserve muscle protein, rebuild muscle protein more rapidly, and hence get their strength back faster. (Specification, page 3, lines 14-21.)

In addition, it has now been found that a composition for a nutritional supplement in accordance with the invention, because it contains whey protein, is easier to digest. Therefore, the problem of a patient not consuming a sufficient amount of the supplement may be reduced. Similarly, the problem of a patient not consuming sufficient other foods may be reduced. Further, the composition has a well balanced lipid profile which provides a readily available energy source. (Specification, page 2, lines 22-27.)

Preferably, the whey protein hydrolysate represents a minimum of 50% of the protein content in the formulation. It is preferably the sole protein source but may be combined with intact whey protein or other protein or peptide sources including peptides naturally found in whey or milk such as caseino glycomacropeptide (CGMP). Surprisingly, it has been found that despite the high proportion of partially hydrolyzed protein in the composition, it is physically stable and has a very acceptable taste due to the process used to prepare the hydrolysate and the selection of a flavoring system to give an acceptable organoleptic profile. (Specification, page 4, lines 12-19.)

Preferably, the protein source provides about 8% to about 20%, more preferably an embodiment for adults comprises a protein source which provides about 15% to about 18% (most preferably about 16%) of total energy of the composition. An alternative embodiment is suitable for children and it comprises a protein source which provides about 8% to about 14% (most preferably about 12%) of total energy of the composition. (Specification, page 4, lines 23-27.)

Remarkably, because of the nature of the whey protein and the fact that it increases protein synthesis and it is capable of being easily digested, the composition has a beneficial effect in persons requiring a nutritional supplement such as those suffering from muscle mass depletion and/or with limited appetite, such as those suffering or recovering from trauma, illness, or surgery, the elderly or those who have problems digesting other sources of protein such as persons having chronic gastritis who are known to have a reduced gastric pepsin digestion. Remarkably, the composition enables such persons to retain or regain their strength quickly and therefore helps aid recovery of a convalescing patient. (Specification, page 4 line 28 – page 5, line 4.)

Preferably, the lipid source comprises about 40% to about 65% by weight of monounsaturated fatty acids; and about 15% to about 30% by weight of polyunsaturated fatty acids. The saturated fatty acid content is preferably less than about 30% by weight. Up to 20% by weight of medium chain triglycerides may be incorporated into the fat blend to facilitate digestion. The lipid source may contain at least about 30 mg of vitamin E per 100 g of lipid source. Preferably, the lipid source provides about 25% to about 35% of total energy of the composition, more preferably about 30% of total energy of the composition. (Specification, page 5, lines 5-12.)

The carbohydrate source comprises sucrose, corn syrup, maltodextrin or a combination thereof. Generally, the carbohydrate source provides about 50% to about 60% of total energy of the composition. Preferably, an embodiment of the composition has a micronutrient composition having a unique profile rich in nutrients including one or more selected from the group which comprises Vitamin E, Vitamin C, taurine, folic acid and vitamin B-12. Remarkably, the profile aids replenishment of nutrients required in higher quantities during periods of illness or recovery due to oxidative stress or inflammatory conditions and nutrients such as vitamin B-12 that may be poorly absorbed in those suffering from digestive disorders such as chronic gastritis or those who have undergone major intestinal surgery. (Specification, page 5, lines 16-23.)

Another advantage of the present invention is that a preferred embodiment is rich in Vitamin E and Vitamin C, and as such, can be used to replete levels of these nutrients in the blood following depletion related to infection, sepsis or other oxidative stress. Preferably, an embodiment additionally comprises taurine and as such can be used to replete levels of taurine in the blood following depletion related to infection, sepsis or other oxidative stress. (Specification, page 6, lines 23-28.)

VI. ISSUES

The issues on Appeal are as follows:

1. Would Claims 1-4, 6-12, 15-23, and 26-34 have been obvious to one skilled in the art at the time of Appellants' invention under 35 U.S.C. § 103(a) in view of U.S.

Patent No. 6,200,950 ("*Mark*") in view of U.S. Patent No. 6,326,355 ("*Abbruzzese*")?*

2. Would Claim 5 have been obvious to one skilled in the art at the time of Appellants' invention under 35 U.S.C. § 103(a) in view of *Mark* and in further view of U.S. Patent No. 6,355,612 ("*Ballevre*"), or alternatively in view of U.S. Patent No. 5,278,288 ("*Kawasaki*") and U.S. Patent No. 5,968,586 ("*Etzel*")?

3. Would Claims 13, 14, 24, 25, 35, and 35 have been obvious to one skilled in the art at the time of Appellants' invention under 35 U.S.C. § 103(a) in view of *Mark* in combination with *Abbruzzese*, and in further view of U.S. Patent No. 6,077,504 ("*Cavaliere*")?

VII. GROUPING OF THE CLAIMS

Appellants argue for the patentability of the independent claims separate and apart from each other unless it is stated differently. Likewise, Appellants argue for the patentability of the dependent claims separate and apart from the independent claims from which they depend unless stated otherwise. The reasons supporting Appellants' position that the claims are separately patentable are provided in §VIII (ARGUMENT) below in accordance with Rule 1.192(c)(8).

VIII. ARGUMENT

A. THE CLAIMED INVENTION -- INDEPENDENT CLAIMS

Of the claims on appeal, Claims 1, 15 and 26 are independent claims. These independent claims provide as follows:

1. A method for improving muscle protein synthesis comprising the steps of administering a therapeutically effective amount of a composition comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source, whey protein, a lipid source having an omega 3 to 6 fatty acid ratio

* A copy of each reference cited by the Examiner is attached hereto as Exhibits B-G, respectively.

of approximately 5:1 to about 10:1 and which provides at least 18% of the total calories of the composition, a carbohydrate source, and a micronutrient profile comprising at least vitamin E and vitamin C.

15. A method for preventing muscle loss in an individual at risk of same comprising the steps of administering a therapeutically effective amount of a composition comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source including whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least 18% of the total calories of the composition, a carbohydrate source, and a micronutrient profile comprising at least vitamin E and vitamin C.

26. A method for accelerating muscle mass recovery comprising the steps of administering a therapeutically effective amount of a composition to an individual comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source including whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least about 18% of the total calories of the composition, a carbohydrate source; and a micronutrient profile comprising at least vitamin E and vitamin C.

B. THE REJECTIONS

In the Final Office Action, Claims 1-4, 6-12, 15-23 and 26-34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Mark* in view of *Abbruzzese*. In this regard, the Office Action states in relevant part:

> Mark et al. disclose a method of administering a therapeutic composition containing protein, in the amount of 15-20% which can be hydrolyzed whey protein (col. 3, lines 35-55) (with 100% being from hydrolyzed whey protein as in claim 4), a lipid source which can be omega-6 to omega-3 ratio of 7:1 in the amount of 20-50% (col. 4, lines 34-47), vitamins, and minerals which are known to include A and E (col. 4, lines 48-54) and a carbohydrate source such as maltodextrin, corn starch, sucrose and corn syrup (col. 4, lines 6-14). Claims 1-4, 6, 9-12 differ from the reference in the amount of fat which is required and in using in particularly vitamins E and C. However no patentable distinction is seen in the use of 18% and the lower level of 20% which is

disclosed by the reference at this time absent anything unobvious in a difference of 2%. Also, Abbruzzese et al. disclose a composition containing omega 3 fatty acids which contains an antioxidant system, which includes vitamins C and E (abstract). Therefore, it would have been obvious to use amounts a little lower than cited by the reference.

Claim 7 further requires particular amounts of monunsaturated fatty acids and polyunsaturated fatty acids and claim 8 particular amounts of saturated fatty acids. Mark et al. disclose the use of canola oil, corn oil and soybean oil all of which contain both mono and polyunsaturated fatty acids. The particular amounts are seen as within the skill of the ordinary worker, as the beneficial effects of the oils are well known, absent any unexpected results using the particular amounts of oils. Certainly, in these oils the amount of saturated fatty acids would have bee [sic] less than 30%. Therefore, it would have been obvious to use known oils in the particular amounts in the claimed composition.

The limitations of claims 15-23, 26-34 have been disclosed above and are obvious for those reasons. Any various in amounts are seen as within the skill of the ordinary worker.*

Claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mark* in view of *Ballevre*, or alternatively in view of *Kawasaki* and *Etzel*. In this regard, the Office Action states in relevant part:

Ballevre et al. disclose a protein composition containing caseinoglycomacropeptide (GMP), which can be used in a nutritional supplement (col. 12, lines 20-21, lines 40-60). Also, Kawasaki et al. disclose that it is known to use GMP's in the field of food and medical supplies (col. 5, lines 60-64). Etzel disclose that it is known to use GMP as a nutraceutical in foods and medicine (col. 1, lines 25-35). Therefore, it would have obvious to use GMP in other nutritional formulas for its known function of providing protein.

In addition, Claims 13, 14, 24, 25, 35 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mark* in view of *Abbruzzese*, and in further view of *Cavaliere*. In this regard, the Office Action states in relevant part:

Claim 13 further requires various kinds of prebiotic fiber. Cavaliere et al. 6,326,000 disclose a composition containing bifidobacterium and fiber such as inulin and

* Appellants wish to note for the record that the while these claims include similar language they are clearly drawn to different subject matter. As such, Appellants believe this portion of the rejection is uninformative and improper because the reasons for rejection are not "fully and clearly stated." See MPEP §707.07(d).

oligosaccharides (abstract and col. 5, lines 40-55). Therefore, it would have been obvious to add prebiotics to the composition for their known function of increasing the bacteria in the intestine.*

C. THE APPLICABLE LAW

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference

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* Once again, Appellants take issue with the form of this rejection as it provides no reasoning whatsoever as to how one would be motivated to combine these references.

teachings. Second, thee must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1999); MPEP 2142. In this regard, the Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention" *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

In ascertaining the appropriateness of a particular reference as the basis for a rejection under § 103, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Core & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984). Accordingly, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983).

Moreover, the Federal Circuit has held that "obvious to try" is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). "An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claim result would be obtained if certain directions were pursued." *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

D. *MARK* IN VIEW OF *ABBRUZZESE* DOES NOT RENDER OBVIOUS ANY OF CLAIMS 1-4, 6-12, 15-23, AND 26-34

As noted above, independent Claims 1, 15, and 26 are directed to a method for improving muscle protein synthesis, a method for preventing muscle loss in an individual at risk of same, and

a method for accelerating muscle mass recovery, respectively. Appellants submit that *Mark* in view of *Abbruzzese* does not disclose or suggest such methods.

Mark relates to general nutritional compositions. As admitted by the Examiner, *Mark* does not disclose or suggest using a micronutrient profile comprising at least vitamin E and vitamin C or Appellants' claimed lipid percentage. See Office Action of October 11, 2002 at 3. Moreover, this reference clearly does not disclose or suggest a method for improving muscle protein synthesis, a method for preventing muscle loss, or a method for accelerating muscle recovery. Indeed, *Mark* does not even mention the word "muscle" at all within the entire text. *Mark* only states that the compositions are utilized to treat metabolically stressed patients, which are defined as "patients who, due to either a disorder or condition, are unable to tolerate whole protein diets and need fluid restriction, while at the same time cannot tolerate elevated protein levels or excess fluid." See col. 6, lines 13-20. Thus, there is no mention or suggestion whatsoever that the composition could be used for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery.

The Examiner states "the use of a protein source to improve muscle protein synthesis is well known as this is the function of protein in a diet." See Final Office Action at 2. The Examiner further posits "the use of lipids and carbohydrates has a protein sparing effect as lipids keep protein or tissue from being burned for energy." While some of this may be true, this is a complete mischaracterization of Appellants' claimed invention.* As is clear from the claims, the invention is directed to methods which are performed using a specific nutritional composition. As this composition is not exactly disclosed in the prior art, it hardly makes sense that methods--also not disclosed or suggested--for using such a composition would be "obvious."

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* Contrary to the Examiner's suggestion, protein in the diet serves far more than the mere function of "improving muscle protein synthesis." For example, protein in the human body is constantly being broken down and resynthesized and provides the source of amino acids for other metabolic pathways such as the synthesis of glucose and fat. Also, it is estimated that humans obtain between 10-12% of our total energy needs from protein.

Further supporting Appellants' position is the Examiner's own citation. *Mark* states that "protein concentration of the present invention is optimal for **moderate tissue repair** needs of the targeted patient populations without imposing an undue burden nitrogen burden on renal function." See *Mark*, col. 3, lines 40-44 (emphasis added). As described in one of the very references cited by the Examiner, tissue repair is associated with wound healing, and has nothing to do with stimulating muscle synthesis. See *Ballevre*, col. 2, lines 17-18.

In addition, to what type of tissue is this referring? It appears the Examiner is taking the position that tissue repair is synonymous with muscle protein synthesis. However, as is well known, there are four primary types of tissue in the human body and as discussed above, and muscle is notably absent from the disclosure of *Mark*. There is no doubt the compositions of *Mark* are being used only for general nutritional purposes and the Examiner certainly has not established otherwise. As such, Appellants submit the methods of the instantly claimed invention are not disclosed or suggested anywhere in *Mark*.

Abbruzzese suffers from at least the same infirmities as *Mark*. For example, *Abbruzzese* relates to methods of inhibiting metabolic and cytokine associated features of cachexia as well as reducing oxidative damage and anticancer drug-induced immuno-suppression in a cancer patient. See col. 3, lines 11-25. There is simply no suggestion for using the composition in *Abbruzzese* in a method for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. The composition disclosed in *Abbruzzese* is primarily designed to inhibit signal transduction and cytokine activity. See col. 6, lines 20-25. Moreover, the use of antioxidants in *Abbruzzese* is intimately related to their use as cancer reducing agents, not for any properties related to muscle growth or maintenance. See col. 7, lines 5-15. The only mention of the word "muscle" in *Abbruzzese* is "skeletal muscle wasting" which appears in a laundry list of symptoms that may be associated with cancer cachexia. See col. 1, lines 45-60. Thus, there certainly is no specific disclosure or suggestion concerning a method of improved muscle synthesis, preventing muscle loss, or accelerating muscle recovery.

Further, even if the disclosure of *Abbruzzese* could be combined with *Mark*, the proposed combination would still not render the claimed invention obvious. In this regard, there simply is

no mention or suggestion for using any of the compositions, in either of these references, in the manner as set forth in the pending claims. Accepting, *arguendo*, the Examiner's position that the instantly claimed compositions are disclosed/suggested in the cited references it is established law that new and non-obvious uses of old compositions may be patentable. See MPEP §2112.02. In this regard, neither of the cited references, alone or in combination disclose or suggest a method for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery.

What the Examiner clearly has done is to simply piece together the cited references by selectively picking and choosing teachings of each of the references in an attempt to recreate what the claimed invention discloses. Of course, the Court of Appeals for the Federal Circuit has criticized this motivation to combine analysis as being "hindsight reconstructive" because the motivation to combine the references was first disclosed in the present invention. *In re O'Farrell,* 853 F.2d., 894, 902-903 (Fed. Cir. 1988). Accordingly, Appellants respectfully submit that the obviousness rejection of Claims 1-4, 6-12, 15-23 and 26-34 should be reversed.

E. *MARK* IN FURTHER VIEW OF *BALLEVRE* OR *KAWASAKI* AND *ETZEL* DOES NOT RENDER OBVIOUS CLAIM 5

As discussed in detail above, *Mark* fails to teach or suggest all of the features of the claimed invention. Moreover, *Ballevre* or *Kawasaki* and *Etzel* do not remedy the deficiencies of *Mark.*

Ballevre relates to the use of protein material whose rate of digestion has been reduced and a composition including the same. See col. 1, lines 8-15. However, *Ballevre* is completely silent as to methods for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. As set forth above, the claims of the present invention are limited to such methods.

The Examiner states "it would have been obvious to use GMP in other nutritional formulas for its known function of providing protein." See Office Action of October 11, 2002 at 4. However, *Ballevre* does not disclose or suggest any special properties for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. It is established law that the mere fact that references are combinable does not render the combination obvious unless the prior art suggests the desirability of the combination. See *In re Mills*, 916 F.2d 680 (Fed. Cir.

1990) and MPEP 2143.01. Where is the suggestion to combine GMP with the teachings of *Mark*? Put another way, why would one skilled in the art pick GMP over the myriad of other potential sources of protein that are available for use with the nutritional supplements of *Mark*?

Appellants submit that once again the Examiner has mischaracterized the invention. The motivation in the present case is not to provide a protein source, but rather to provide a protein source in a nutritional composition for use in methods for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. As was explained in detail above, protein -- even in a nutritional supplement -- can be used for a number of different reasons. Neither of these references teach or suggest any uses for GMP in a nutritional composition used for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery.

Kawasaki and *Etzel* similarly fail to remedy the deficiencies of *Mark*. Neither *Kawasaki* nor *Etzel* discloses or suggests methods for improving muscle synthesis, preventing muscle loss, or accelerating muscle recovery. For example, *Kawasaki* is directed to a method of production of GMP. *Kawasaki* does mention that GMP can be used in food, but it does not mention anywhere any properties related to improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. Once again, all the Examiner has done is provided a reference which discloses GMP generally. Completely missing from the Examiner's analysis is any specific instruction as to why one skilled in the art would choose to incorporate GMP into the nutritional composition described in *Mark*.

Equally flawed is the Examiner's reliance on *Etzel*. *Etzel* is directed to a process for producing kappa-casein macropeptides having nutraceutical properties from cheese whey using two ion exchangers of opposite polarity in series. See col. 1, lines 12-16. Much like the other references, *Etzel* does not mention anywhere that GMP can be used in a nutritional composition for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. In addition, the Examiner has failed to provide any rationale as to why one skilled in the art would combine *Etzel* with *Mark*. Indeed, with respect to both *Kawasaki* and *Etzel*, Appellants are unclear as to how one skilled in the art would be apprised of either of these references at all as they are so far afield from the subject matter of the instant invention.

Once again the Examiner has improperly engaged in selectively picking and choosing isolated teachings from each of the references in an attempt to recreate what the claimed invention discloses. As discussed above, this motivation to combine analysis is "hindsight reconstructive" and impermissible within the context of an obviousness rejection. Accordingly, in view of the foregoing, Appellants submit that these rejections under 35 U.S.C. §103(a) are in error and should be reversed.

F. *MARK* IN VIEW OF *ABBRUZZESE*, AND IN FURTHER VIEW OF *CAVALIERE* DOES NOT RENDER OBVIOUS CLAIMS 13, 14, 24, 25, 35, AND 36

The short comings of the combination of *Mark* and *Abbruzzese* are discussed above and for the sake of brevity will not be repeated here. Appellants submit that *Cavaliere* fails to remedy the deficiencies of this combination of references on several fronts.

Once again the Examiner's rejection misses the mark. The Examiner states as follows:

> "*Cavaliere* discloses a composition containing bifidobacterium and fiber such as inulin and oligosaccharides. Therefore it would have been obvious to add prebiotics to the composition for their known function of increasing the bacteria in the intestine."

Appellants recognize that *Cavaliere* discloses the above combination. However, nowhere in *Cavaliere* is it mentioned that the disclosed compositions can be included in nutritional compositions used in methods for improving muscle protein synthesis, preventing muscle loss, or accelerating muscle recovery. *Cavaliere* generally touches on the concept of inclusion in conventional nutritional supplements, however as pointed out again and again this is not Appellants' claimed invention. The several nutritional compositions of the prior art do not achieve the unexpected results described in Appellants' specification. Moreover, even if those references are combined, there is no disclosure of the methods of the claimed invention. Accordingly, Appellants submit that Claims 13, 14, 24, 25, 35, and 36 are patentable over this combination of references and respectfully request that this rejection be reversed.

IX. CONCLUSION

Appellants' claimed invention set forth in Claims 1-36 is neither taught nor suggested by the cited references, either alone or even in combination. The Patent Office has failed to establish a *prima facie* case of obviousness with respect to the rejections of Claims 1-36. Accordingly, Appellants respectfully submit that the rejections of pending Claims 1-36 as obvious are erroneous in law and in fact and should therefore be reversed by this Board.

Respectfully submitted,

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BY 

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APPENDIX

CLAIMS

1. A method for improving muscle protein synthesis comprising the steps of administering a therapeutically effective amount of a composition comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source, whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least 18% of the total calories of the composition, a carbohydrate source, and a micronutrient profile comprising at least vitamin E and vitamin C.

2. The method of Claim 1 wherein the whey protein includes a partially hydrolyzed whey protein.

3. The method of Claim 1 wherein the whey protein includes a whey protein hydrolysate that comprises at least 50% of the protein source in the composition.

4. The method of Claim 1 wherein at least 50% by weight of the whey protein is hydrolyzed.

5. The method of Claim 1 wherein the composition includes caseino glycomacropeptide.

6. The method of Claim 1 wherein the protein source provides up to about 20% of the total energy of the composition.

7. The method of Claim 1 wherein the lipid source comprises about 40% to about 65% by weight of monounsaturated fatty acids and about 15% to about 30% by weight of polyunsaturated fatty acids.

8. The method of Claim 1 wherein the saturated fatty acid content is less than 30% by weight.

9. The method of Claim 1 wherein the lipid source provides approximately 25% to about 35% of total energy of the composition.

10. The method of Claim 1 wherein the carbohydrate source comprises sucrose, corn syrup, maltodextrin or a combination thereof.

11. The method of Claim 1 wherein the carbohydrate source provides approximately 50% to about 60% of total energy of the composition.

12. The method of Claim 1 wherein the micronutrient composition includes one or more micronutrients selected from the group consisting of: Vitamin E, Vitamin C, taurine, folic acid and vitamin B-12.

13. The method of Claim 1 which comprises at least one prebiotic fiber selected from the group consisting of: inulin; acacia gum; resistant starch; dextran; xylo-oligosaccharide ; fructooligosaccharide (FOS); and combinations thereof.

14. The method of Claim 1 including at least one probiotic micro-organism.

15. A method for preventing muscle loss in an individual at risk of same comprising the steps of administering a therapeutically effective amount of a composition comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source including whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least 18% of the total calories of the composition, a carbohydrate source, and a micronutrient profile comprising at least vitamin E and vitamin C.

16. The method of Claim 15 wherein the whey protein includes a partially hydrolyzed whey protein.

17. The method of Claim 15 wherein the whey protein includes a whey protein hydrolysate that comprises at least 50% of the protein source in the composition.

18. The method of Claim 15 wherein at least 50% by weight of the whey protein is hydrolyzed.

19. The method of Claim 15 wherein the protein source provides up to about 20% of the total energy of the composition.

20. The method of Claim 15 wherein the lipid source comprises about 40% to about 65% by weight of monounsaturated fatty acids and about 15% to about 30% by weight of polyunsaturated fatty acids.

21. The method of Claim 15 wherein the saturated fatty acid content is less than about 30% by weight.

22. The method of Claim 15 wherein the lipid source provides approximately 25% to about 35% of total energy of the composition.

23. The method of Claim 15 wherein the micronutrient composition includes one or more micronutrients selected from the group consisting of: Vitamin E; Vitamin C; taurine; folic acid; and vitamin B-12.

24. The method of Claim 15 which comprises at least one prebiotic fiber selected from the group consisting of: inulin; acacia gum; resistant starch; dextran; xylo-oligosaccharide; fructooligosaccharide; and combinations thereof.

25. The method of Claim 15 including at least one probiotic micro-organism.

26. A method for accelerating muscle mass recovery comprising the steps of administering a therapeutically effective amount of a composition to an individual comprising: a protein source which provides at least 8% of the total calories of the composition and which includes at least 50% by weight, of the protein source including whey protein, a lipid source having an omega 3 to 6 fatty acid ratio of approximately 5:1 to about 10:1 and which provides at least about 18% of the total calories of the composition, a carbohydrate source; and a micronutrient profile comprising at least vitamin E and vitamin C.

27. The method of Claim 26 wherein the whey protein includes a partially hydrolyzed whey protein.

28. The method of Claim 26 wherein the whey protein includes a whey protein hydrolysate that comprises at least 50% of the protein source in the composition.

29. The method of Claim 26 wherein at least 50% by weight of the whey protein is hydrolyzed.

30. The method of Claim 26 wherein the protein source provides up to about 20% of the total energy of the composition.

31. The method of Claim 26 wherein the lipid source comprises about 40% to about 65% by weight of monounsaturated fatty acids and approximately 15% to about 30% by weight of polyunsaturated fatty acids.

32. The method of Claim 26 wherein the saturated fatty acid content is less than about 30% by weight.

33. The method of Claim 26 wherein the lipid source provides approximately 25% to about 35% of total energy of the composition.

34. The method of Claim 26 wherein the micronutrient composition includes one or more micronutrients selected from the group consisting of: Vitamin E; Vitamin C; taurine; folic acid; and vitamin B-12.

35. The method of Claim 26 which comprises at least one prebiotic fiber selected from the group consisting of: inulin; acacia gum; resistant starch; dextran; xylo-oligosaccharide; fructooligosaccharide; and combinations thereof.

36. The method of Claim 26 including at least one probiotic micro-organism.

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EXAMINER
PRATT, HELEN F

ART UNIT	PAPER NUMBER
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5-12-03

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/821,498	Applicant(s) FUCHS ET AL.
	Examiner Helen F. Pratt	Art Unit 1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-12, 15-23, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Abbruzzese et al.

The claims are rejected for the reasons of record cited in the last office action

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. as applied to the above claims, and further in view of Ballevre et al. or Kawasaki et al. and Etzel.

The claims are rejected for the reasons of record cited in the last office action.

Claims 13, 14, 24, 25, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Abbruzzese et al. as applied to claims 1-4, 6-12, 15-23, 26-34 above, and further in view of Cavaliere et al.

The claims are rejected for the reasons of record cited in the last office action.

ARGUMENTS

Applicant's arguments filed 1-13-02 have been fully considered but they are not persuasive. Applicants argue that Mark et al. does not teach a method for improving muscle protein synthesis and other improvements. However, the use of a protein source to improve muscle protein synthesis is well known as this is the function of protein in the diet. Certainly, the use of lipids and carbohydrates has a protein sparing

effect as lipids keep protein or tissue from being burned for energy. The above is known nutritional information. No patentable distinction is seen at this time in the use of 18% fat and the lower level of 20% disclosed by the reference. Mark et al. is used in combination with Abbruzzese et al. to show that it is known to use omega 3 fatty acids and vitamin C and E, one of whose function is to act as antioxidants. A metabolically stressed patient as in Abbruzzese et al. is one who would need protein synthesis. Applicants' invention is also directed to stressed individual as those who are ill due to oxidative stress or inflammatory conditions (page 5, lines 16-24). Also, col. 3, lines 40-4, disclose that the protein concentration of the reference is optimal for moderate tissue repair i. e. protein promotes tissue repair. Vitamins E and C are disclosed in the reference and C in more than the daily requirement as is vitamin E (col. 6, lines 55-66 and col. 7, lines 1-30). In fact, Abbruzzese et al. disclose the use of more vitamin E and C per serving (page 14 top of specification compared to col. 7, of Mark et al. No data is seen that anything unexpected happens in the combination of ingredients, and particular ratios, that more protein synthesis occurs using the instant invention as opposed to the combined references.

Applicants argue as to Abbruzzese that there is no suggestion in Abbruzzese to improve protein syntheses. However, the reference discloses that the nutritional composition is to promote "maintenance and repair of body tissue", i. e. protein synthesis as tissue is made from protein (col. 16, lines 1-12). Also, in col. 7, lines 25-35,the composition is used to provide nutritional support due to nutritional deterioration,

or to rehabilitate the depleted patient. This would of course include adequate amounts of protein to build tissue.

Applicants argue that Ballevre or Kawasaki or Etzel do not teach the whole invention. However, these references are used to show that it is known to use GMP in nutritional supplements. The reason to use GMP in protein synthesis is that it provides protein nutrition, and provides a hydrolyzed, nonbitter ingredient (col. 3, lines 20-44 of Ezel). The GMP of Kawasaki is another source of protein. Nothing is seen that it produces unexpected results in the instant invention. The GMP of Ballevre et al. can be used in compositions to provide dietary proteins to promote body growth (col. 5, lines 40-44) (this includes production of tissue and muscle provided as a function of proteins).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 703-308-1978. The examiner can normally be reached on Monday 4-10, Tuesday and Wednesday, Friday, from 9:30 to 6:00 and Thursday 4-10.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is 703-305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

Hp 2-5-03

H. Pratt

HELEN PRATT
PRIMARY EXAMINER